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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/512,829	02/25/2000	David S. Garvey		6724

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EDWARD D GRIEFF  
HALE & DORR LLP  
1455 PENNSYLVANIA AVE, NW  
WASHINGTON, DC 20004

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

18

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/512,829

Applicant(s)  
Garvey et al.

Examiner  
Deepak Rao

Art Unit  
1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 25, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 36-45, 50, 51, 59, 60, 64, 66, 68, 71, 72, and 79-84 ☒ are pending in the application.
- 4a) Of the above, claim(s) 42-45, 71, and 72 ☒ are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-41, 50, 51, 59, 60, 64, 66, 68, and 79-84 ☒ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3, 4, 14, 17 6) ☐ Other:

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#### DETAILED ACTION

Claims 36-45, 50-51, 59-60, 64, 66, 68, 71-72 and 79-84 are pending in this application.

#### *Election/Restriction*

Applicant's request for reconsideration of the restriction requirement in paper no. 16 has been acknowledged. Upon reconsideration and based on the assertion by applicant that independent claims 50, 64, 59, 66 and 68 are all drawn to treatment of **gastrointestinal disorders**, Groups I-IV of the previous office action are rejoined as a single Group I and examined together.

Applicant's election of Group I (revised as per the proposal in paper no. 16, page 3) in Paper No. 16 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 71-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made without traverse in Paper No. 16.

Applicant's election of the species of **lansoprazole** as the proton pump inhibitor and **S-nitrosogluthione** as the compound that donates, transfers or releases nitric oxide, induces the production of endogenous nitric oxide or endothelium derived relaxing factor, or a substrate of

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nitric oxide synthase, is acknowledged. As the respective species were found in the prior art, the examination was limited to the elected species. MPEP § 803.02.

Claims 42-45 drawn to other compounds that donate, transfer, or release nitric oxide, etc., and the remaining proton pump inhibitor compounds and NO donating compounds from the claims under consideration (i.e., claims 50-51, 59-60, 64, 66, 68, 36-41 and 79-84) are additionally withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the claim, it is recited that “S-nitrosothiol is: (i).... (ii).... **and** (iii)....”, wherein it is not clear, how the claimed S-nitrosothiol can be all of (i), (ii) and (iii). Replacing ‘and’ with -- or -- is suggested.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 50-51, 59-60, 64, 66, 68, 36-41 and 79-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over [Nohara et al., U.S. Patent No. 4,628,098 or Depui et al., WO 97/25064 or WO 96/24375] and Stamler et al., U.S. Patent No. 5,380,758.

Nohara et al. (US'098), teaches benzimidazole compounds including lansoprazole that are useful in treating gastrointestinal disorders, see formula (I) in the reference and the specific compound in claim 10.

Depui et al. (WO'064) teaches proton pump inhibitors that are useful in the treatment of gastrointestinal disorders and exemplifies lansoprazole (see page 10, second compound).

WO'064 teaches the combination of the proton pump inhibitor with a NSAID, which NSAID's include selective COX-2 inhibitors and NO releasing NSAID's (see page 13, lines 1-2) and

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antacid formulations (see page 17, lines 7+), however, the reference does not exemplify a S-nitrosothiol.

Also, see WO'375 which discloses lansoprazole (page 8, third compound) and teaches the use of the proton pump inhibitor compounds in treatment of disorders associated with *Helicobacter pylori*. Further, WO'375 teaches that combination therapy of these diseases with bismuth compounds, see page 1, second paragraph.

Stamler et al., US'758 in the analogous art teaches S-nitrosothiols including S-nitrosoglutathione (see col. 10, line 36) that have gastrointestinal therapeutic activity (see col. 9, lines 34-47). Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of the above references because he would have had the reasonable expectation that the composition comprising the individual compounds of the references would have the same therapeutic activity as taught for each of the compounds. [T]he idea of combining the references flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Applicant's arguments in paper no. 13 have been fully considered but they were not deemed to be persuasive. Applicant argues that Nohara and Depui do not disclose or suggest a compound that donates, transfers or releases nitric oxide and Stamler does not disclose proton pump inhibitors. However, as provided in the previous office action, one of ordinary skill in the art would have expected the combination of the compounds taught for the same use to have enhanced use for the same therapeutic utility. The combination of the individual teachings of the

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references is further obvious in view of the teachings of combination therapy, see e.g., WO'375.

Applicant has not provided any evidence to the contrary.

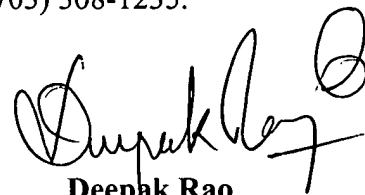
Receipt is acknowledged of the Information Disclosure Statements filed on April 11 and 20, 2000 and December 13, 2001 and copies are enclosed herewith.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Deepak Rao', with a stylized flourish at the end.

**Deepak Rao  
Primary Examiner  
Art Unit 1624**

December 15, 2002